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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,269	07/11/2001	Asa Berglund	003300-790	2429

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,269

Applicant(s)

BERGLUND, ASA

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-16 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-16 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/12/04 & 6/17/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to your remarks filed 2/18/2004. Claims 1-5, 8-16 and 20 are pending and rejected.
2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112, withdrawn

3. Applicant's arguments are persuasive and have obviated the rejection under 35 USC 112, second paragraph for being indefinite for claims 1-5, 8-16 and 20.

Claim Rejections - 35 USC § 103, withdrawn

4. Rejections of claims 1-5 and 10-16 are under 35 U.S.C. 103(a) as being unpatentable over Goren et al. (1986) in view of Zahorska et al. (1995) is withdrawn in light of Applicants arguments with reference to Zahorska et al.'s teachings. The Office does agree that the inducer of the interferon production taught by Zahorska is not viral.

Claim Rejections - 35 USC § 103, maintained

5. Claims 8, 9 and 20 remain rejected under 35 USC § 103(a) as being unpatentable over Goren et al. (1986) in view of Johnston (U.S. Patent No: 4,780,413) for reasons set forth in Office Action of 10/20/03 pages 4 and 5. Further claims 1-4 and 10-13 are also rejected over Goren et al. (1986) in view of Johnston (U.S. Patent No: 4,780,413). Applicant's arguments filed on 2/18/2004 have been considered but are not persuasive. Applicant is arguing that the secondary reference of Johnston fails to remedy the deficiencies of the primary reference and fails to provide the motivation to combine the two references.

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Johnston reference was included in the previous Office Action to teach increased production of interferon- α following the induction of leukocytes with virus and the subsequent treatment of infected cells with pyrrolidones and other cyclic amides. The human lymphoblastoid cells used in the production of interferon- α are an established cell line derived from peripheral human blood leukocytes. Contrary to Applicant's assertion that the "primary human white blood cell are unfit for the production of suitable amounts of interferon- α for clinical purposes", Johnston, reference only recites that the "primary human white blood cells cannot provide abundant amounts of interferon- α " (column 1, lines: 17-20). Therefore, to boost the production of interferon, Johnston teaches the use of an inducer (column 1, lines: 30-45). Although, there are often differences between cell lines and primary cells both the lymphoblastoid cells and peripheral human blood leukocytes absent evidence to the contrary produce interferon- α following viral induction of the cells, organic compounds and solvents are used for enhancement of viral production. Thus, motivating one of skilled in the art to use pyrrolidones and other cyclic amides (inducers) to boost the production of interferon- α following the viral induction. Contrary to Applicants assertion that the pretreatment with sodium butyrate acts as a stimulant in EP No: 0097353 to produce interferon, Johnston in both EP No: 0097353 and U. S. Patent No: 4,780,413 (see Table II) show conflicting results with respect to the stimulatory effect of sodium butyrate. Finally, with reference to Applicant's assertion that Johnston reference teaches away from instant invention because it states that "primary human white blood cells cannot provide abundant amounts of interferon- α " (column 1, lines: 17-20),

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further reading of Johnston teaches that the above reference was for the production of interferon- α in the absence of using enhancing agents (see columns 1 and 2). Furthermore, the use of primary cells including monocytes and lymphocytes to produce interferon- α " was taught by Goren (1986). It should be noted that, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Therefore, claims 1-4 and 8-13 are rejected as being obvious over Goren et al. (1986) in view of Johnston (U.S. Patent No: 4,780,413) is maintained.

Claim Rejections - 35 USC § 103

6. Claims 5 and 14-16 are rejected under 35 USC § 103(a) as being unpatentable over Goren et al. (1986) in view of Johnston (U.S. Patent No: 4,780,413) and Slattery et al. (1984), see 1449 of 6/27/2001.

The teachings of Goren et al. and Johnston have been described in Office Action of 10/20/2003 (paragraphs 4a and 4b) and above in paragraph 5.

Slattery et al. teaches the use of theophylline to enhance the production of interferon following the induction Ehrlich ascites NDV virus (see abstract and Fig.1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to enhance the interferon production following the induction with virus of human monocyte and lymphocytes, as described by Slattery et al., because Slattery et al. teaches that the addition of Theophylline, a xanthine derivative increase the production of interferon. One of ordinary skill in

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the art would have been motivated to increase the production of interferon for clinical purposes. Thus the claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary. Therefore, the instant invention is obvious over Goren et al. (1986) in view of Johnston (U.S. Patent No: 4,780,413) and Slattery et al. (1984), see 1449 of 6/27/2001.

7. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS
07/04


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